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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,227	ITO ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,22 and 24-42* is/are pending in the application.

4a) Of the above claim(s) *1-13,25,26,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-19,22,24,27-37 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/14/06, 10/3/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19, 22, 24-42 are pending in the instant application.

Election/Restriction

1. Applicant's election with traverse of Group II (claims 14-19, 22, 24, 27-37 and 40-42 drawn to a method of treating inflammatory bowel disease by administering an antibody against IL-6 receptor protein (10/6/06) is acknowledged. The traversal is on the ground(s) that the restriction is improper since this case is a divisional of a national stage application and is governed by PCT Rule 13, Unity of Invention. However, contrary to Applicants argument, the instant case is a divisional of 09/646,188 which is a 371 of PCT/JP99/01298. The instant case is not a divisional of a national stage application. Only for applications which are 371's of PCT applications, PCT Rule 13, Unity of Invention applies. Therefore, Applicants arguments are not found persuasive. The Groups as delineated in the restriction requirement (10/4/06) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13, 25-26, 38-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be

amended to recite "a method of treating inflammatory bowel disease by administering an antibody to the IL-6 receptor".

Claim rejections-35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27-37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims embrace a use of IL-6 antagonist and there are no provisions for "a use" in the statutes. Amending the claims to recite "a process or a method" will obviate this rejection, but does not prevent the Examiner from making the next office Action final.

In view of the improper format for claims 27-37, these claims will be examined for a reasonable interpretation of their intended meaning.

Claim rejections-35 USC § 112, scope of enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 14-19, 22, 24, 27-37, 40-42, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating inflammatory bowel disease by administering effective amount of monoclonal antibody, PM-1 or MR16-1 against the human IL-6 receptor, does not reasonably provide enablement for a method of preventing or treating inflammatory bowel disease by administering "all" IL-6 antagonists. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification delimits the instant antibodies to be used in the claimed method by reference to specific antibodies PM-1 and MR16-1. However, claim 14 recites IL-6 antagonist, wherein the term itself does not represent any distinguishing information concerning the IL-6 antagonist. Claims that lack the recitation of structural properties of the antagonist encompass subject matter not supported by the instant specification. IL-6 antagonist molecules that are embraced by the claims are not adequately supported by the instant specification because the specification provides no guidance for how to make such molecules nor are examples provided as to how these molecules would be identified commensurate with the breadth of the claims. In the absence of an appropriate structural and/or functional reference, a person of ordinary skill in the art would be unable to make and use the antagonist molecules embraced by the claims without undue experimentation because one could not distinguish the antagonist molecules envisaged by the specification and those which are unrelated.

With respect to claim 14, as recited, what is claimed in the method of the instant invention broadly encompasses administering "all" IL-6 antagonists. While the specification discloses that anti-IL-6 receptor antibodies MR16-1 and PM-1 were administered (see Example on pages 33-35), the specification is non-enabling for the unlimited number of IL-6 antagonist compositions which are encompassed by the scope of the claims. Claim 14 is a single means claim (M.P.E.P. 2164.08(a)). In In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), the Courts have held that: "A single means claim, i.e. where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection

under 35 U.S.C. 112, first paragraph." (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor). Since no material limitations for the antagonist have been recited in the claim and only a biological activity has been recited, the claim encompasses every conceivable structure (means) for achieving the stated property (result), a fact situation comparable to Hyatt. Therefore, not only proteins, such as antibodies against IL-6 receptor, but all other proteins which exhibit an antagonist activity to IL-6 receptor such as variants of IL-6 that are antagonists of the IL-6 receptor, are encompassed by the scope of the claim. The claimed invention encompasses a method of administering compositions not envisioned or described in the specification, and neither does the specification disclose how these claimed compositions can be distinguished from each other. The specification only enables a method of administering PM-1 and MR16 antibodies to treat inflammatory bowel disease, these antibodies having specific characteristics and properties. These properties may differ structurally, chemically and physically from other known proteins. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine which other IL-6 antagonists are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little, thereby rendering the results of the assays taught in the specification unpredictable (see pages 33-35). Therefore, it would require undue experimentation to determine which IL-6 antagonists having the desired biological

activity of treating inflammatory bowel disease would be encompassed by the scope of the claims. The disclosure of two monoclonal antibodies to be used in the claimed method is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass every and all IL-6 receptor antagonists including mutants of IL-6. In In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), the Courts have held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Furthermore, the amount of embodiments corresponding to the desirable compositions, may be innumerable, and the enabled embodiments amount to only two. Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The

specification does not describe any other IL-6 receptor antagonists to be used in the claimed method other than PM-1 and MR16-1, and since it is deemed to constitute undue experimentation to determine all the others, the disclosure is not commensurate with the scope of the claims. Therefore, Applicants are not enabled for a method of treating inflammatory bowel disease using anything less than antibodies PM-1 and MR16-1. It is suggested that by employing conventional claim language, the claims be amended to include the specific antibodies to be used in the claimed method as supported by the instant specification.

Furthermore, claim 14 recites "preventing" inflammatory bowel disease. The instant specification is non-enabling for a method of preventing inflammatory bowel disease because one of ordinary skill in the art would have to predict in advance which patients are susceptible to inflammatory bowel disease in order to administer to the patients antibodies PM-1 and MR16-1. There are no working examples of administering these antibodies to a prospective patient of inflammatory bowel disease. The skilled artisan would not know in advance which patient will be susceptible to the disease and cannot do so based on the teachings in the prior art or specification. The claims are broad and the specification does not provide guidance for a method of preventing inflammatory bowel disease in a patient.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art, and lack of knowledge about administering the antibodies to prevent inflammatory bowel disease in a patient, the two limited working examples of administering PM-1 and MR16-1 antibodies, the lack of direction or guidance for using any other IL-6 receptor antagonist, and the breadth of the claims for function without structure, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claim rejections-35 USC § 112, written description

4b. Claims 14-19, 22, 24, 27-37 and 40-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14, for example, is drawn to a method of treating inflammatory bowel disease by administering an IL-6 antagonist. The claims do not require that the antagonist possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a method of administering a genus of IL-6 antagonists that is defined only by function, i.e. treat inflammatory bowel disease

To provide adequate written description and evidence of possession of a claimed genus of antagonists to be administered in the claimed method, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial biological activity in the form of a recitation of a function. There is not even identification of any particular portion of a structure that must be conserved. As stated above, it is not even clear what region of the antagonist has the disclosed activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, such as structure of the antagonist, the specification does not provide adequate written description of the claimed genus of antagonists.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of antagonists, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a method of treating inflammatory bowel disease by administering an effective amount of antibodies PM-1 and MR16-1 to a patient suffering form said disease but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-19, 22, 24, 27-37, 40-42, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is rejected as vague and indefinite because the limitation "an IL-6 antagonist" is improper. The antibody antagonist to be administered in the claimed method is not "an IL-6 antagonist" but "an IL-6 receptor antagonist".

Similarly, claim 27 is rejected as vague and indefinite for the recitation of "IL-6 antagonist".

Claims 15-19, 22, 24, 28-37, 40-42 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim rejections-Double Patenting

Non-statutory double patenting rejection (obviousness-type)

6. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and 8 may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6a. Claims 14-19, 22, 24, 27-37 and 40-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,723,319 ('319). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-4 of '319 (having all three common inventor with the instant application), claims a method of treating inflammatory bowel disease with specific antibodies PM-1 and MR16-1. In instant claim 14, for example, the claimed method for treating inflammatory bowel disease encompasses administering an IL-6 antagonist. Instant claims 14-19, 22, 24, 27-37 and 40-42 are generic to claims 1-4 in '319 and encompasses subject matter to which the issued claims in '319 are a species because instant claims 14-19, 22, 24, 27-37 and 40-42 encompass the claims in '319. However, the claims in '319 are obvious from the instant claims because the claims in '319 are directed to specific embodiments encompassed by instant claims 14-19, 22, 24, 27-37 and 40-42. The issued method in '319 is included in instant claims 14-19, 22, 24, 27-37 and 40-42. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that instant claims 14-19, 22, 24, 27-37 and 40-42 included the issued claims in '319. Allowance of the pending claim,

therefore, would have the effect of extending the enforceable life of the allowed claims in US Patent 6,723,319 beyond the statutory limit.

Claim rejections-35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7a. Claims 14, 15, 16, 17, 18, 19, 24, 27-32, 37, are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/38481.

WO 96/38481 teaches a monoclonal antibody to the human cytokine receptor gp 130 and a method of treating inflammatory bowel disease by administering the antibody (see abstract; see claims 1-6; page 1, lines 35-37; page 2, lines 1-5; page 4, lines 23-35; page 11, lines 5-17 and Figures 3A-3B and 4). The reference discloses that the cellular signals via IL-6 binding to its receptor are transduced via a common receptor β chain subunit known as gp130 (CD130) (page 1, lines 25-34).

With respect to claim 18, the reference teaches a method of treating a mammal, which includes antibodies to a mouse IL-6 receptor. With respect to claim 24, the reference teaches a method of treatment of ulcerative colitis (page 3, lines 31-36). With respect to claims 19, 32, which recite "recombinant antibody", where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a

sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See also In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971).

The WO 96/38481 reference teaches the administration of monoclonal antibodies to the IL-6 receptor in a method of treating inflammatory bowel disease (page 4, lines 23-35). Therefore, the method disclosed in reference meets the limitations recited in claims 14, 15, 16, 17, 18, 19, 24, 27-32, and 37.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8a. Claims 22, 35, 40-42 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 96/38481 in view of Queen et al. (U.S. Pat No. 5,530,101).

WO 96/38481 discloses a monoclonal antibody to the human cytokine receptor gp 130 and a method of treating inflammatory bowel disease by administering the antibody as set forth above in paragraph 7. WO 96/38481 fails to disclose a chimeric antibody or a humanized antibody against the IL-6 receptor.

Queen et al., (column 17, lines 31-43) teaches the production of antibody fragments, including the Fab fragment, and the production of chimeric antibodies and the humanization of monoclonal antibodies, as well as the issues involved in designing a humanized antibody that retains high affinity for its antigen. (column 11, lines 52-65 and 58-67; column 13, lines 5-65).

Therefore, at the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to administer as taught by Queen et al, humanized monoclonal antibodies to IL-6 receptor for treating inflammatory bowel disease in a patient in a method as taught by WO 96/38481. The motivation for doing so would have been the decreased immunogenicity of humanized antibodies when injected into humans, while the humanized antibodies retain their affinity for their epitope (Queen et al, (column 2, lines 5-8)).

Conclusion

No claim is allowed.

Claims 14-19, 22, 24, 27-37, 40-42 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
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Art Unit 1646
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